EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Constella

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: linaclotide

Procedure No. EMEA/H/C/002490/PSUV/0009

Period covered by the PSUR: 26.11.2012 – 26.05.2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Constella, the scientific conclusions of PRAC are as follows:

During the reporting interval for this PSUR, no new signals were identified but two were refuted by the MAH. Gastrointestinal bleeding was not confirmed as a signal as concomitant conditions or medications present alternative, more plausible aetiologies for the events. This is agreed. However, refuting hypersensitivity reactions (mainly rash) is not finally agreed as there have been an overall of 29 cases including hypersensitivity reactions, nine cases considered having a positive dechallenge and one with even a positive rechallenge.

Therefore, in view of available data regarding linaclotide, the PRAC considered that changes to the product information were warranted. The MAH should include rash in section 4.8 of the SmPC and the corresponding section of the PL. As overall limited data was available due to the short observational period since launch the MAH is requested to keep the signal “hypersensitivity reactions” open and present interval and cumulative data on the issue within the next PSUR.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Constella, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance linaclotide is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.